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10/582,423

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BRUSCA, JOHN S

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/582,423	<b>Applicant(s)</b> GORSE, ALAIN-DOMINIQUE JEAN-PIERRE	
	<b>Examiner</b> John S. Brusca	<b>Art Unit</b> 1631	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 29 October 2009.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-19,23,24,33,34,37 and 38 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-4 and 6-19 is/are allowed.
- 6) ☒ Claim(s) 5,23,24,33 and 34 is/are rejected.
- 7) ☒ Claim(s) 37 and 38 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>11/13/2009</u> . | 6) <input type="checkbox"/> Other: _____  |

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## **DETAILED ACTION**

### ***Status of the Claims***

1. Claims 1-19, 23, 24, 33, 34, 37, and 38 are pending.

Claims 5, 23, 24, 33, and 34 are rejected.

Claims 37 and 38 are objected to

Claims 1-4 and 6-19 are allowable.

2. It is noted that the Office action mailed 02 June 2009 contained an error on the Office action summary in listing claims 1-19 as subject to a restriction requirement. Claims 1-19 should have been listed as allowed, as indicated on page 2 of the Office action.

3. This Office action contains new grounds of rejection not necessitated by the applicant's amendment filed 29 October 2009 under 35 U.S.C. 112, first and second paragraph, 35 U.S.C. 102(b), and 35 U.S.C. 103(a), and is therefore a non-final Office action.

### ***Information Disclosure Statement***

4. The information disclosure statement (IDS) submitted on 03 November 2009 is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner with the exception of those references lined through on the list of references attached to this Office action. The Information Disclosure Statement filed 03 November 2009 does not contain a legible copy of each reference listed on the list of references. It is not known whether this is an error of the applicants or a scanning error by the Office. Consequently the missing references have been listed as not considered in the signed copy of the list of references attached to this Office action. If the applicants provide a legible

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copy of the missing references in response to this Office action, the references will be considered under 37 CFR 1.97(f), and a signed copy of the list of references indicating consideration of the missing references will be provided to the applicants without the necessity of the applicants filing a second Information Disclosure Statement.

***Claim Objections***

5. The objections to claims 32 and 39 in the Office action mailed 02 June 2009 is withdrawn in view of the cancellation of the claims in the amendment filed 29 October 2009.

***Claim Rejections - 35 USC § 101***

6. The rejection of claim 45 under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter in the Office action mailed 02 June 2009 is withdrawn in view of the cancellation of the claim in the amendment filed 29 October 2009.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 33 and 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

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art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The claims include compositions that have a generic target molecule with no structural limitations. The specification describes target molecules that are antibodies that are bound by Protein A or Protein G to a surface by the Fc region of the antibody (see page 26, Table 1, and pages 36-43). The specification does not provide examples or structures of target molecules that could be used in the claimed compositions other than antibodies. One of skill in the art would not understand that the applicants had in their possession the full genus of target molecules without structural limitation that could be a part of the claimed compositions.

9. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 5 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 5 and 24 are indefinite for recitation of the phrases "Fab fragment" and "Fc fragment" because it is not clear if the phrases are meant to refer to an antibody target molecule that is a fragment, or to a region of an antibody target molecule. For the purpose of examination the phrases are assumed to mean regions rather than fragments.

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***Claim Rejections - 35 USC § 102***

11. The rejection of claims 20-22, 25-32, 35, 36, and 40 under 35 U.S.C. 102(b) as being anticipated by Turkova in the Office action mailed 02 June 2009 is withdrawn in view of the cancellation of the claim in the amendment filed 29 October 2009.

12. It is brought to the Applicant's attention that a product by process claim is examined for novelty and obviousness of the claimed product only, and that no consideration is given to the novelty or obviousness of the method of making the claimed product. See M.P.E.P. 2113.

13. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

14. Claims 23 and 24 are rejected under 35 U.S.C. 102(b) as being anticipated by Turkova (Journal of Chromatography B, Vol. 722, pages 11-31 (1999)).

The claims are drawn to binding surfaces made by the process of claim 1 comprising an antibody target molecule that binds an antigen. The target molecule is bound to a surface so that the antibody binding site is available to bind the antigen. The antigen binds at the Fab region and the antibody is bound to the surface by the Fc region.

Turkova reviews oriented proteins bound to a substrate. Turkova shows on the second column of page 13 that immobilized Protein A binds to the Fc region of antibodies, and allows

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for the Fab region of the antibody to be free to bind antigen. Figure 1 depicts immobilized Protein A that orients immunoglobulin molecules so that they can bind antigen.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

15. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over Turkova in view of Penzol et al. (Biotechnology and Bioengineering Vol. 60, pages 518-523 (1998)).

The claims are drawn to binding surfaces made by the process of claim 1 comprising a target molecule. The target molecule is bound to a surface by pendant groups on a polymer backbone comprising a spacer.

Turkova reviews oriented proteins bound to a substrate. Turkova shows on the second column of page 13 that immobilized Protein A binds to the Fc region of antibodies, and allows for the Fab region of the antibody to be free to bind antigen. Figure 1 depicts immobilized Protein A that orients immunoglobulin molecules so that they can bind antigen.

Turkova does not show Protein A comprising a spacer.

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Penzol et al. shows in the abstract, figure 2, Table II, and pages 520-521 that use of dextran 6,000 spacers aids in the ability of antibodies to bind to Protein A. Penzol et al. states on page 521 that the spacer prevents steric hindrance promoted by the support.

It would have been obvious to a person of ordinary skill in the art at the time the invention was made to modify the Protein A used by Turkova by use of Protein A linked to a spacer because Penzol et al. shows that Protein A linked to a spacer has improved ability to bind to antibodies. Regarding the limitation of pendant groups on a polymer, Protein A is a polypeptide comprising groups that bind antibodies and therefore Protein A meets the limitations of the claimed polymer backbone.

#### ***Allowable Subject Matter***

16. Claims 1-4, and 6-19 are allowable.
17. Claims 37, and 38 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. An objection to claim 39 is detailed above.

#### ***Conclusion***

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to John S. Brusca whose telephone number is 571 272-0714. The examiner can normally be reached on M-F 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Marjorie A. Moran can be reached on 571-272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/John S. Brusca/

Primary Examiner, Art Unit 1631

jsb